K071281

Péters SURGICAL

AUG - 3 2007

SECTION 11

510(k) SUMMARY

[As Required by 21 CFR 807.92(c)]

Information supporting claims of substantial equivalence, as defined under the Federal Food, drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

510(k) Summary Date prepared April 27, 2007

510(k) Submitter

PETERS SURGICAL
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Official Correspondent

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Quality Director
PETERS SURGICAL Bobigny, FRANCE, 93013
Phone: 33-148-106254

New Device Name

Trade name: UNIRING® - Annuloplasty ring with sizers
Common/Usual name: Annuloplasty Ring
Classification name: Ring, Annuloplasty

New Device Classification

Class II in 21 CFR §870.3800 by the Cardiovascular Device Classification Panel, Annuloplasty Ring (KRH).

Predicate Device Name

Northrup Universal Annuloplasty System - K033685

CarboMedics AnnuloFlex Annuloplasty System - K992056

Edwards Lifesciences Cosgrove-Edwards Annuloplasty System – K923367

Baxter Carpentier-Edwards Physio Annuloplasty Ring – K926138

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Statement of intended use

The UNIRING® is indicated as reinforcement for repair of the human cardiac mitral and tricuspid valves damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring. The annuloplasty ring should be used only in cases where visual inspection confirms that the valve is repairable and does not require replacement.

New Device Description

The UNIRING® consists of an annuloplasty ring mounted on a holder assembly for implantation in the mitral or tricuspid position. A complete set of instrumentation is available separately to properly size the annulus.

Summary of Technological Characteristics of New Device compared to Predicate Device(s)

The UNIRING® is a flexible annuloplasty ring that can be implanted either as a partial or complete ring, according to the surgeon's preference and/or patient condition. For purposes of this submission, the UNIRING® was compared to the following predicate device(s):

- Northrup Universal Annuloplasty System - K033685
- CarboMedics AnnuloFlex Annuloplasty System - K992056
  - can be implanted either as a partial or complete ring with identical function as the Northrup Universal Annuloplasty System
- Edwards Lifesciences Cosgrove-Edwards Annuloplasty System – K923367
- Baxter Carpentier-Edwards Physio Annuloplasty Ring – K926138

Performance data

Non-clinical laboratory testing was performed demonstrating that the device complied with the USP Monographs and with the EP Monographs for Absorbable surgical sutures.
The results of biocompatibility testing support that the materials used in the manufacture of the UNIRING® are non-toxic, non-hemolytic, and non-pyrogenic. All testing was conducted under Good Laboratory Practices per 21 CFR Part 58. Mechanical Integrity testing for the UNIRING® includes suture retention testing which demonstrated that the design provided for a more than adequate retention force as compared to the predicate device. Testing demonstrated that the UNIRING® is substantially equivalent to the predicate device for repair of the mitrial or tricuspid valve.

Conclusions

Based on the 510(k) summary (21 CFR 807) and the information provided herein, we conclude that our Medical Device UNIRING® is substantially equivalent to the Predicate devices under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2007

Peters Surgical
c/o Mr. Robert Renault
Quality Director
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42 Rue Benoit Franchon
Bobigny, France 93013

Re: K071281
UNIRING – Annuloplasty Ring with Sizers
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty ring
Regulatory Class: Class II (two)
Product Code: KRH
Dated: May 7, 2007
Received: May 7, 2007

Dear Mr. Renault:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 10

STATEMENT OF INDICATIONS FOR USE

510(k) Number K071281

Device Name UNIRING® Annuloplasty Ring with sizers

Indications for use

The UNIRING® is indicated as reinforcement for repair of the human cardiac mitral and tricuspid valves damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring. The annuloplasty ring should be used only in cases where visual inspection confirms that the valve is repairable and does not require replacement.

Prescription Use _x_ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071281